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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Imad Ed. Tarabishy

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07/12/2006

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EXAMINER

BLANCO, JAVIER G

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/799,192	TARABISHY, IMAD ED.	
	Examiner	Art Unit	
	Javier G. Blanco	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 26, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12 is/are allowed.
- 6) ☒ Claim(s) 1,5,8,10 and 11 is/are rejected.
- 7) ☒ Claim(s) 2-4,7 and 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/27/2005</u> <u>JB</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claims 1, 2, 5, 7, 8, 10, 11, and 12 in the reply filed on April 26, 2006 is acknowledged.

Claim Objections

2. Claim 10 is objected to because of the following informality: please substitute "shaft includes a neck" (see line 8) with --shaft includes said neck--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 10 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a. Regarding claim 10, the limitation "having a ball formed thereon" (see lines 8 and 9) was not disclosed or suggested in the specification. Claim 10, at line 8, already introduced the limitation "a ball attached to said neck". The limitation "having a ball formed thereon" gives the

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impression that there is a second ball attached to the shaft, which subject matter was not

disclosed or suggested in the specification and/or drawings. Claim 11 depends on claim 10.

Because of the procedure outlined in M.P.E.P. 2163.06 for interpreting the claims, it is noted that other art may be applicable under 35 U.S.C. 102 or 35 U.S.C. 103(a) once the aforementioned problem is corrected.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1 and 5 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Maumy et al. (US 5,725,590 A).

Referring to Figures 1a, 2a-2c, and 3b, Maumy et al. disclose a joint prosthesis comprising:

(i) A segmented shell (metallic outer shell 1) having an interior surface and separate segments (e.g., element 20, outer shell segment 1b, outer shell segment 1c; see column 3, lines 12-67);

(ii) A second shell (spherical cap 22) fixedly retained within said interior surface of said segmented shell (see column 4, lines 1-35);

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(iii) A cup (inner shell 31), having an exterior surface *sized and configured to be fixedly retained* (emphasis added to functional language) in said second shell; and

(iv) A shaft (Figure 1a: stem 10) having a first end and a second end, said shaft comprising a body, a neck (neck 184) attached to said body, and a ball (not shown in Figures, but well known in the art) attached to said neck at said first end of said shaft, said ball received by said cup (as visible from the inner surface of inner shell 31) *for movement therein* (emphasis added to functional language).

7. Claims 1, 5, and 8 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Hyde, Jr. (US 6,589,281 A; previously cited in PTO-892).

Referring to Figures 20-22 (see column 20, line 40 to column 21, line 40), Hyde, Jr. discloses a joint prosthesis comprising:

(i) a segmented shell (base 195 comprises segments 194 and/or 196) having an interior surface (see Figures 21 and 22);

(ii) a second shell (acetabular assembly 191) fixedly retained within said interior surface of said segmented shell and comprising a plurality of segments (modules/segments 192);

(iii) a cup (cup 193), having an exterior surface *sized and configured to be fixedly retained* (emphasis added to functional language) in said second shell; and

(iv) a shaft having a first end and a second end, said shaft comprising a body (core implant module 182 and/or modular stem 150), a neck (neck 184) attached to said body, and a ball (head 183) attached to said neck at said first end of said shaft, said ball received by said cup *for movement therein* (emphasis added to functional language).

Hyde, Jr. discloses (see column 20, line 40 to column 21, line 40) the structure of the second shell (acetabular assembly 191) as claimed in claim 8. It should be noted that several dictionaries (i.e. Merriam-Webster online dictionary; www.dictionary.com) define "shell" as: "An external case or outside covering", "A framework or exterior structure".

Response to Arguments

8. Applicant's arguments filed April 26, 2006 have been fully considered but they are not persuasive. The Applicant argues that Hyde, Jr. '281 does not disclose a second shell. The Examiner respectfully disagrees. Several dictionaries (i.e. Merriam-Webster online dictionary; www.dictionary.com) define "shell" as: "An external case or outside covering", "A framework or exterior structure". As noted above (102(e) rejection), the Examiner considers base 195 as the first segmented shell. Base 195, as a whole, comprise two segments (e.g., base + lip) or several segments (e.g., threads). The Examiner considers modules/segments 192 as the plurality of parts of the second shell. It is the Examiner's opinion that the language of claims 1 and 8 could be improved by indicating "a segmented shell having an interior surface and a plurality of separate segments" (or similar language).

9. Claims 1 and 5 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Afriat et al. (WO 01/35873 A1; also published as US 6,811,569 B1).

Referring to Figures 1-3, Afriat et al. disclose a joint prosthesis comprising:

- (i) a segmented shell (acetabular cup 2) having an interior surface;
- (ii) a second shell (intermediate element 3) fixedly retained within said interior surface of said segmented shell;

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- (iii) a cup (plastic insert 4), having an exterior surface *sized and configured to be fixedly retained* (emphasis added to functional language) in said second shell; and
- (iv) a shaft (Figure 1) having a first end and a second end, said first end of said shaft having a ball (see Figure 1) formed thereon that is received by said cup *for movement therein* (emphasis added to functional language).

Afriat et al. disclose acetabular cup 2 as comprising a plurality of longitudinally and transversely arcuate segments 7 pivotally engaging a base (polar cap P2). Said plurality of segments form a cup-shaped segmented shell (see Figures 1-3).

Response to Arguments

10. Applicant's arguments filed April 26, 2006 have been fully considered but they are not persuasive. The Applicant argues that Afriat et al. does not disclose a segmented shell. The Examiner respectfully disagrees. As the Applicant admits (see page 10 of the Response), acetabular cup 2 comprises segments 7. It is the Examiner's opinion that the language of claims 1 and 8 could be improved by indicating "a segmented shell having an interior surface and a plurality of separate segments" (or similar language).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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12. Claims 10 and 11 are rejected, as best understood (see 112 1st paragraph rejection above), under 35 U.S.C. 103(a) as being unpatentable over Hyde, Jr. (US 6,589,281 A; previously cited in PTO-892) in view of Grimes (WO 00/48535 A1; previously cited in PTO-892).

Hyde, Jr. discloses the invention as claimed in claims 1, 5, and 8. Although Hyde, Jr. discloses the desirability of preventing/removing wear debris and introducing therapeutic agents into the joint area (something which is well known in the art), he/she did not particularly disclose the stem or shaft as having a set of channels with a structure (i.e., a first main channel having dual open ends, a second main channel having an open end and a closed end; secondary channels interconnecting with one of the main channels) as disclosed in claims 10 and 11.

However, that structure is known in the art. For example, Grimes discloses a joint prosthesis comprising a shaft having: (i) at least one tube (primary channel 616) having first and second open ends and extending from the bottom surface of said body and opening through said neck (see Figures 29 and 30); (ii) a second tube (primary channel 614) having an open end extending from the bottom surface of said body and a second closed end (see Figures 29 and 30); and secondary tubes (secondary channels 635-639) passing through a side wall of said body and through said second tube such that said secondary tubes are in fluid communication with said second tube in order to apply cement to the prosthesis-bone interface, remove wear debris, and/or introduce therapeutic agents into the joint area (see Figures 29 and 30; see page 46, lines 7-24; see entire document). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teachings of a joint prosthesis stem/shaft having at least one tube having first and second open ends, a second tube having an open end and a second closed end, and secondary tubes passing through a side wall of said body

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and through said second tube, as taught by Grimes, with the joint prosthesis shaft/stem of Hyde, Jr., in order to apply cement to the prosthesis-bone interface, remove wear debris, and/or introduce therapeutic agents into the joint area.

With regards to Applicant's argument "Grimes fails to establish prima facie obviousness", Grimes clearly states at page 30, lines 22-24 the desirability of total hip replacement comprising preparing the acetabulum in order to receive a prosthetic socket (acetabular cup). One of ordinary skill in the art would have been left to devise or select an appropriate acetabular cup.

the art at the time the invention was made to have combined the teachings of a joint prosthesis stem/shaft having at least one tube having first and second open ends, a second tube having an open end and a second closed end, and secondary tubes passing through a side wall of said body and through said second tube, as taught by Grimes, with the joint prosthesis shaft/stem of Afriat et al., in order to apply cement to the prosthesis-bone interface, remove wear debris, and/or introduce therapeutic agents into the joint area.

Allowable Subject Matter

13. Claims 2-4, 7, and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. Claim 12 is allowed.

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Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Doursounian (WO 2000/09045 A1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

June 30, 2006



David H. Willse
Primary Examiner